UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspio.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/597,559	12/07/2006	Emi Sumida	20080-00005	2846	
35736 JHK LAW				EXAMINER	
P.O. BOX 1078			HANLEY, SUSAN MARIE		
LA CANADA, CA 91012-1078			ART UNIT	PAPER NUMBER	
			1651		
			MAIL DATE	DELIVERY MODE	
			05/12/2009	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
	10/597,559	SUMIDA ET AL.			
Office Action Summary	Examiner	Art Unit			
	SUSAN HANLEY	1651			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  If NO period for reply is specified above, the maximum statutory period was Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	<b>N.</b> nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status					
1) Responsive to communication(s) filed on 21 Au	<u> </u>				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	53 O.G. 213.			
Disposition of Claims					
4) Claim(s) 1-20 is/are pending in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.					
6) Claim(s) is/are rejected.					
7) ☐ Claim(s) is/are objected to.					
8) Claim(s) <u>1-20</u> are subject to restriction and/or e	election requirement.				
Application Papers					
9) The specification is objected to by the Examine	r.				
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.					
Applicant may not request that any objection to the	drawing(s) be held in abeyance. See	e 37 CFR 1.85(a).			
Replacement drawing sheet(s) including the correcti	on is required if the drawing(s) is ob	jected to. See 37 CFR 1.121(d).			
11)☐ The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.			
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:	priority under 35 U.S.C. § 119(a)	)-(d) or (f).			
1. Certified copies of the priority documents	s have been received.				
2. Certified copies of the priority documents	s have been received in Applicati	on No			
3. Copies of the certified copies of the prior	ity documents have been receive	ed in this National Stage			
application from the International Bureau	ı (PCT Rule 17.2(a)).				
* See the attached detailed Office action for a list	of the certified copies not receive	ed.			
Attachment(s)					
1) Notice of References Cited (PTO-892)	4) Interview Summary	,			
Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO/SB/08)     Paper No(s)/Mail Date	Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:				

Art Unit: 1651

## **DETAILED ACTION**

## Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-7 and 15-19, drawn to a method to prepare a platelet rich plasma by adding a polymer with an organic phosphate to blood.

Group II, claim(s) 8-10 and 20, drawn to a platelet-rich plasma.

Group III, claim(s) 11, drawn to therapeutic methods with a platelet-rich plasma.

Group IV, claim(s) 12 and 13, drawn to drawn to a polymer having an organic phosphate residue.

Group V, claim(s) 14, drawn to a device for preparing a platelet-rich plasma.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I is the adding of two components, blood and a polymer having a residue of an organic phosphate compound to selectively precipitate erythrocytes.

The special technical feature of Group I is a composition of plasma with platelets and not erythrocytes.

The special technical feature of Group III is a method of treating a person or a medical/dental item by applying a platelet-rich plasma to said person or item for a therapeutic outcome.

Art Unit: 1651

The special technical feature of group IV is a polymer which is a large molecule with repeating units having an organic phosphate residue.

The special technical feature of Group V is a device that is a machine consisting of parts that can perform at least a mixing function.

Group II lack the special technical feature of Group I becasue it does not involve physical steps of adding two separate components, blood and a polymer having an organic phosphate residue.

Group II lacks the special technical feature of Group III because it does not involve a physical step of applying a platelet-rich plasma to a person or medical/dental device for a therapeutic outcome.

Groups II, IV and V lack the same corresponding technical feature because a plateletrich plasma consists of cells (platelets) in a physiological solution while a polymer is a large molecule of repeating units and a device is a machine that performs a particular function of at least mixing.

Groups I and III lack a corresponding technical feature because Group I is directed to addition steps of two separate components for making a platelet-rich plasma while Group III is directed to using said plasma in steps that involve its application to a person or medical/dental device for a therapeutic outcome.

Group I lacks the same corresponding special technical feature with groups IV or V becasue it is a method directed to addition steps of two components for making a platelet-rich plasma while group IV is a polymer that is a is a large molecule of repeating units and a device is a machine that performs a particular function of at least mixing.

Group III lacks the same corresponding special technical feature with groups IV or V becasue it is a method directed to a therapeutic method that involves applying or administering a platelet-rich plasma to a person or medical/dental device for a therapeutic outcome while group IV is a polymer that is a is a large molecule of repeating units and a device is a machine that performs a particular function of at least mixing.

Groups IV and V lack the same corresponding special technical feature because a polymer is a large molecule consisting of repeating units of atoms with an organic phosphate residue while a device that can make a platelet-rich plasma is a machine that performs at least a mixing function.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

A polymer specie that is Formula IV, V, VI or VII.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 3-7 and 15-19.

The following claim(s) are generic: 1, 2, 8-11 and 20.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The polymers contain monomers of different residues, some of which are not organic phosphate residues, such that the combination of monomers will cause the polymers to have different physical and chemical properties.

Art Unit: 1651

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/597,559 Page 7

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sandra Saucier/ Primary Examiner, Art Unit 1651

/Susan Hanley/ Examiner, Art Unit 1651